Remarks

Claims 1-45 are pending in the application.

§ 103 Rejection of Curtet in view of Kerč

Claims 1-45 are rejected under 35 U.S.C. § 103 as being obvious over Curtet et al (U.S. Patent No. 4,895,726) in view of Kerč et al (U.S. Patent No. 6,042,847).

Applicants respectfully traverse the rejection and respectfully submit that neither Curtet nor Kerč disclose or suggest the claimed capsules having the claimed fenofibrate to polymer ratio of between 1:10 and 4:1. *See* independent claims 1, 11, 18, 25, 34 and 40.

Curtet provides working examples comprising 200 grams fenofibrate and 7 grams cross-linked polyvinylpyrrolidone,[1] such that the weight ratio of fenofibrate to cross-linked polyvinylpyrrolidone is 29:1. Neither Curtet nor Kerč provide any motivation or suggestion to drastically reduce the weight ratio of fenofibrate to cross-linked polyvinylpyrrolidone (PVP) of 29:1 in Curtet to fall within the claimed range of fenofibrate to polymer of between 1:10 and 4:1. The weight ratio in Curtet is significantly different than the claimed weight ratio and there is no motivation or suggestion in any of the references to arrive at the claimed weight ratio of between 1:10 and 4:1. The ratio of fenofibrate to polymer in Curtet has greater than 7 times more fenofibrate to cross-linked PVP than the claimed ratio of fenofibrate to polymer. There is no motivation in any of the references to drastically reduce the ratio used in Curtet to arrive at the claimed invention.

The PTO asserts that Applicants failed to show the criticality of the claimed ratio. Applicants respectfully disagree. Moreover, Applicants respectfully submit that the PTO has not established a *prima facie* case of obviousness for the reasons discussed above and that any "criticality" is irrelevant in view thereof.

Curtet corresponds to EP-A-0330532 which is discussed in the specification at page 2, lines 1-20 and Examples 2-4. Curtet corresponds to Lipanthyl® 200M in Figures 1 and 2 in the present application.

The dissolution medium and conditions in the present claims are a rotating blade method

[1] Curtet at column 2, lines 30-40 and column 2, line 65 to column 3, line 5.

at 75 rpm, where the dissolution medium is water with 2% polysorbate 80 or water with 0.025 M sodium lauryl sulfate. In contrast, Curtet uses a rotating vane or continuous flow cell where the dissolution medium is water with 0.1 M sodium lauryl sulfate. The dissolution medium of Curtet comprises much more sodium lauryl sulfate (i.e., surfactant) than the dissolution medium of the claimed invention. Having more surfactant will necessarily enhance dissolution. Accordingly, it is necessary to compare the composition described in the Curtet reference and the claimed composition using the same method. This was done in the present application.

Applicants have shown in Example 2 and Figure 1 of the present application that the claimed invention has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M, as described by Curtet. For the Examiner's convenience, a comparison of the dissolution profile recited in the claims with the dissolution profile of Curtet (i.e., Lipanthyl® 200M) is shown in the Table below.

Time	% Dissolution of Claimed Invention described in Specification	% Dissolution by Inventive Example shown in Example 2 of the Application	% Dissolution by Curtet as Lipanthyl® 200M shown in Example 2 of the Application
30 minutes	at least 75%	95.9%	54.9%

As shown from the summary above, Example 2 and Figure 1 in the application demonstrate that Curtet does not have a dissolution profile like the one which can be achieved with the claimed fenofibrate:polymer ratio. In fact, the claimed invention has an unexpectedly superior profile when compared to Curtet's Lipanthyl® 200M.

Applicants also refer to the Declaration under 37 CFR § 1.132 by Pascale Blouquin (the Blouquin Declaration)[2] to show that the presently claimed invention has unexpectedly superior properties when compared to the dissolution data in the Laboratory Notebooks submitted with the Blouquin Declaration. Blouquin Declaration at ¶ 14. A comparison of the pending claims (i.e., the dissolution which is achieved), the inventive example in the present application and the dissolution data from Lot No. 2177 in the Laboratory Notebook No. 1 at Bates Number Fournier 1001569 is set forth in the table below. Blouquin Declaration at ¶ 14.

[2] The Blouquin Declaration was submitted in the Information Disclosure Statement filed May 6, 2006.

Time	% Dissolution Achieved with Compositions in Pending Claims	% Dissolution by Inventive Example shown in Example 2 of the Application	% Dissolution by Curtet as Lipanthyl® 200M from Lot No. 2177 described in the First Blouquin Declaration and shown in Lab Notebook No. 1 at Fournier No. 1001569	% Dissolution by Curtet as Lipanthyl® 200M from Lot No. 2177 described in Example 2 of the Application
30 minutes	at least 75%	95.9%	67.7%	54.9%
60 minutes	--	--	78%	--

The claimed invention allows achieving 75% dissolution in 30 minutes. The data in the Laboratory Notebook submitted in the Information Disclosure Statement herewith shows that it takes 60 minutes for Curtet's Lipanthyl® 200M to achieve a dissolution of 78%. Blouquin Declaration at ¶ 15. In other words, it takes almost twice as long for Curtet's Lipanthyl® 200M to achieve a dissolution that the claimed fenofibrate composition can achieve in 30 minutes. Blouquin Declaration at ¶ 15. In view of these results, it is Ms. Blouquin's opinion that the claimed invention is superior to Curtet's Lipanthyl® 200M. Blouquin Declaration at ¶ 15.

Applicants respectfully submit that Curtet does not disclose or suggest a composition that exhibits such a dissolution profile with the claimed ratio of fenofibrate:polymer, and that Curtet provides no motivation or suggestion to produce the claimed ratio of fenofibrate:polymer in the composition. In fact, the dissolution profile that can be obtained with the claimed composition is unexpectedly superior when compared to Curtet. Accordingly, Curtet cannot render the claimed invention obvious.

Curtet fails to provide any motivation to modify the fenofibrate:polymer ratio. Indeed, Curtet is solely concerned with co-micronization, and provides no guidance as to the relevancy of the amount of fenofibrate or polymer. Hence, Curtet does not provide the required motivation to modify the ratio to arrive at the claimed ratio.

Kerč does not cure the deficiencies of Curtet. Kerč does not provide any motivation or suggestion to modify the weight ratios of the components in Curtet to arrive at the claimed

weight ratios.[3] This is particularly the case since Curtet teaches relatively fast release fenofibrate compositions when compared to the sustained release compositions described by Kerč. In fact, Kerč teaches away from the claimed invention because Kerč teaches a three-phase pharmaceutical formulation with controlled release properties. Kerč does provide a constant and controlled release formulation (*see* the title and the specification, e.g., the first paragraph in "Technical Field of the Invention"). If Curtet and Kerč were combined, one skilled in the art would be motivated to produce a formulation having controlled or extended release properties by varying the weight ratio of fenofibrate:polymer to produce, i.e., a dissolution profile that is significantly slower than the dissolution profile of the invention. The skilled person would certainly not combine references which have opposite teachings from each other. The skilled person would not combine these references since Kerč's proposed modification (i.e., extended release) would change the principle of operation of Curtet's composition (i.e., relatively faster release than Kerč). *See* MPEP at 2143.02.

In view of the above, Applicants respectfully submit that the presently claimed invention is unobvious over Curtet in view of Kerč and respectfully request that the rejections under § 103 be withdrawn.

[3] Applicants respectfully submit that Kerč does not provide motivation to specifically choose fenofibrate from among the compounds disclosed therein because Kerč only provides working examples that use nifedipine or nicardipine.